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HOIKHMAN=1

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

12/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,593	Applicant(s) HOIKHMAN ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response and Amendment after Non-Final Office Action filed 09/29/10 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of the amendment to the claims and/or persuasive remarks: (1) The objections to specification and claims have been withdrawn; (2) The 35 U.S.C. 112, second paragraph rejections have been withdrawn; (3) The 35 U.S.C. 102(b) rejection of claims 1-5 and 8-10 over Skinner (U.S. Patent No. 6,210,710) has been withdrawn and (4) The 35 U.S.C. 102(b) rejection of claims 1, 3-5, 8 and 10 over Illum (U.S. Patent No. 5,935,604) has been withdrawn.

Claims 1, 3-8 and 10-12 are pending in this action. Claims 1, 3-8 and 10 have been amended. New claim 12 has been added. Claims 2 and 9 have been cancelled. Claim 11 remains withdrawn. Claims 1, 3-8, 10 and 12 are currently under consideration. Claims 1, 3-8, 10 and 12 remain rejected.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-8, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner (U.S. Patent No. 6,210,710).

Skinner ('710) teaches a sustained release pharmaceutical composition comprising a polymer blend formed with a medicament present in a therapeutic amount wherein the polymer blend contains at least a first component and a second component (see column 1, line 4 - col. 2, line 4). A number of polymers may be used in the matrix blend of the invention. Suitable polymers disclosed include hydroxypropylcellulose (HPC), ethylcellulose (EC), hydroxypropylmethylcellulose (HPMC), carboxymethylcellulose (CMC) and the like (col. 2, line 51 – col. 3, line 63). The blend contains at least two components, while even three, four or five

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can be used (col. 2, lines 29-37). These polymers read on the "one or more hydrophilic polymers" claimed by Applicant and thus read on instant claims 1 and 3-4. Examples of suitable polysaccharides employed in the invention are disclosed at column 2, line 64 – col. 3, line 24 and include, for example, gellan gum, guar/guar derivatives, xanthan gum, agar, algin, starch, modified starches and the like. See also claim 1 at column 13. These ingredients can be used alone or as mixtures thereof. These ingredients read on the gellan gum and hydrophilic polymers of instant claims 1 and 3. Drugs are added in the matrix formulation and include, for example, anti-inflammatory substances, stimulants, antihistamines, anti-infectives, vitamins, analgesics and the like (col. 3, line 31 - col. 4, line 33). These drugs read on claim 5. Fillers, excipients, lubricants, flavoring agents, coloring agents, bulking agents and the like are also added (col. 4, lines 46-65). These read on the additives of claim 8 and newly added claim 12. The solid dosage forms can have many forms including a homogeneous or random matrix (tablet) form (col. 5, lines 10-27). Suitable forms also include tablets, lozenges, gelcaps, suspensions, gels and the like (see claim 7 at col. 14). These teachings read on instant claims 1 and 10.

Skinner does not teach that their "drug has preferred absorption in the stomach" (claim 6). Skinner also does not teach the selective drugs of claim 7.

With respect to the limitations of claim 6, it is the position of the Examiner that Skinner meets this limitation. Skinner explicitly teaches controlled or sustained release dosage forms which allow for the delivery of a medicament at an appropriate rate to provide the desired therapeutic activity for a prolonged period of time (col. 1, lines 10-22). The controlled/sustained release formulations of Skinner provide for polymeric blends to delay or control the release of a drug to yield a wide range of release profiles and thus provide improved sustained release

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characteristics (col. 2, lines 8-22). Moreover, Applicant is claiming “the stomach” as a preferred location of absorption. The matrix formulations of Skinner are designed to release drug in the GI tract and would include the “upper parts” or alternatively, “the stomach” claimed by Applicant. “[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). Absent a showing of evidence to the contrary, the formulations of Skinner would also enable absorption at various locations of the GI tract, including the preferred portions (i.e., upper parts/stomach) claimed. Moreover, one of ordinary skill in the art would formulate a controlled or sustained release composition in order to provide for improved therapeutic effects and enhanced bioavailability.

With respect to the limitations of claim 7, it is the position of the Examiner that Skinner also meets this limitation. Skinner explicitly teaches controlled or sustained release formulations comprising drugs that include for example, anti-inflammatory substances, stimulants, antihistamines, anti-infectives, vitamins, analgesics and the like (col. 3, line 31 - col. 4, line 33). These generic classes of drugs read on and encompass the species-specific drugs claimed by Applicant in claim 7. For instance, the reference teaches the inclusion of anti-infectives, which would read on the antibiotics (i.e., clarithromycin, ciprofloxacin) of claim 7.

Hence, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the explicit teachings of Skinner. Skinner teaches a controlled release matrix dosage form comprising the inclusion of polysaccharides (i.e., gellan gum, guar gum, xanthan gum and mixtures thereof) in combination with hydrophilic

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polymers (i.e., CMC, HPMC, etc.) and active ingredients (i.e., anti-infectives). Excipients and additives are also included in the formulation. The dosage forms are suitable for oral administration such as in the form of tablets.

* * * * *

Claims 1, 3-8, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al. (hereinafter "Baichwal") (U.S. Patent No. 5,958,456) in view of Skinner (U.S. Patent No. 6,210,710).

Baichwal ('456) teaches a controlled release formulation comprising active medicaments, formulated as a compressed granulate using a combination of a controlled release excipient comprising a gelling agent and a swelling agent, such as for example, homopolysaccharide gum, a heteropolysaccharide gum and an inert diluent (see column 2, lines 35-41). A preferred heteropolysaccharide gum includes xanthan gum and a preferred homopolysaccharide gum includes locust bean gum (col. 2, lines 42-47). Other acceptable gelling agents disclosed include, for example, alginates, carrageenan, pectin, guar gum, HPMC, sodium carboxymethylcellulose and the like (col. 6, lines 37-45). The diluent can be a saccharide (i.e., lactose) (col. 2, lines 56-64). Suitable active agents are disclosed at column 8, lines 21-65). The dosage form is provided as an oral dosage form (col. 2, lines 48-49), such as in the form of tablets (col. 9, lines 5-21). These teachings read on instant claims 1, 3-5, 8, 10 and newly added claim 12.

With respect to the limitations of claim 6, it is the position of the Examiner that Baichwal meets this limitation. Baichwal explicitly teaches controlled or sustained release dosage forms which allow for the delivery of a medicament at a sustained rate to provide for therapeutically-

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effective blood levels of the medicament activity for a prolonged period of time, e.g., 12 or 24 hours, without allowing an excessive early release of medication, and where the release kinetic are unaffected by the contents of the patients gastrointestinal tract (col. 2, lines 22-30). Moreover, Applicant is claiming "in the stomach" as a preferred location of absorption. The controlled release formulations of Baichwal are designed to release drug in the GI tract and would include the "upper parts" or alternatively, "the stomach" as claimed by Applicant. "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). Absent a showing of evidence to the contrary, the formulations of Baichwal would also enable absorption at various locations of the GI tract, including the preferred portions (i.e., upper parts/stomach) claimed. Moreover, one of ordinary skill in the art would formulate a controlled or sustained release composition in order to provide for improved therapeutic effects and enhanced bioavailability.

With respect to the limitations of claim 7, it is the position of the Examiner that Baichwal meets this limitation. Baichwal explicitly teaches controlled or sustained release formulations comprising drugs that include for example, anti-inflammatory substances, stimulants, antihistamines, antibiotics, vitamins, analgesics and the like (col. 8, lines 21-65). These generic classes of drugs read on and encompass the species-specific drugs claimed by Applicant in claim 7. For instance, the reference teaches the inclusion of antibiotics, which would read on the antibiotics (i.e., clarithromycin, ciprofloxacin) of claim 7.

Baichwal does not teach gellan gum.

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Skinner ('710) teaches a sustained release pharmaceutical composition comprising a polymer blend formed with a medicament present in a therapeutic amount wherein the polymer blend contains at least a first component and a second component (see column 1, line 4 - col. 2, line 4). A number of polymers may be used in the matrix blend of the invention. Polysaccharides employed in the invention are disclosed at column 2, line 64 – col. 3, line 24 and include, for example, gellan gum, guar/guar derivatives, xanthan gum, agar, algin, starch, modified starches and the like. See also claim 1 at column 13. These ingredients can be used alone or as mixtures thereof. Suitable polymers disclosed include hydroxypropylcellulose (HPC), ethylcellulose (EC), hydroxypropylmethylcellulose (HPMC), carboxymethylcellulose (CMC) and the like (col. 2, line 51 – col. 3, line 63). The blend contains at least two components, while even three, four or five can be used (col. 2, lines 29-37). Skinner teaches that the polymeric/polysaccharide blends improve the sustained release characteristics, improve the tablet hardness, tablet friability and produce an overall enhanced tableting performance. The solid dosage forms can be in suitable forms that include tablets, lozenges, gelcaps, suspensions, gels and the like (see claim 7 at col. 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the gellan gum taught by Skinner within the controlled release formulation of Baichwal. One would do so with a reasonable expectation of success because Skinner teaches that the polysaccharide/polymeric blend enables the improvement of sustained release characteristics as well as enhancing overall tableting performance. The expected result would be an improved and effective controlled release formulation for the delivery of therapeutic agents.

* * * * *

Claims 1, 3, 5, 8, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Illum (U.S. Patent No. 5,935,604).

Illum ('604) teaches a drug delivery composition adapted to deliver a pulse of nicotine for rapid absorption and controlled release of nicotine for subsequent sustained absorption. The controlled release phase can be achieved by providing an ion-exchange material, such as a polysaccharide, which will form a complex with the nicotine (see Abstract); (col. 3, lines 21-37). Suitable polymeric materials disclosed include gellan gum, alginate, carboxymethylcellulose (CMC), xanthan gum, agar, guar derivatives and the like. A preferred material is gellan gum (col. 7, lines 23-43). Mixtures of gellan gum with other polymers such as alginate can be used, gelling of the mixture being caused by the gellan gum. The grade of gellan gum can be GELRITE™ or KELCOGEL™ (col. 8, lines 17-33). The examples at columns 10-12 demonstrate various embodiments of the invention. Example 5, for instance, demonstrates a preparation of nicotine alginate gum microspheres, whereby an aqueous solution was prepared containing various amounts of sodium alginate, gellan gum and nicotine dihydrogen tartrate. These teachings read on instant claims 1, 3 and 5. The compositions include pharmacologically-acceptable, non-toxic ingredients such as preservatives, antioxidants, flavorings, etc. (col. 9, lines 13-20). This teaching reads on claim 8 and newly added claim 12. The preparations can be in the form of microspheres that are further packed into gelatin capsules (col. 10, lines 12-16). This teaching reads on claim 10.

* * * * *

Response to Arguments

Applicant's arguments filed 29 September 2010 have been fully considered and were found to be partially persuasive.

▪ **Objections to Specification/Claims:**

Applicant has overcome the objections to specification and claims (recited on pages 3-4 of the Office Action) based on the amendment to the claims and/or persuasive remarks. Accordingly, the objections to claims/specification have been withdrawn.

▪ **Claim Rejections - 35 USC § 112:**

Applicant has overcome the 35 U.S.C. 112, second paragraph rejections (recited on pages 5-6 of the Office Action) based on the amendment to the claims. Accordingly, the 35 U.S.C. 112, second paragraph rejections of claims 5, 6 and 8 has been withdrawn.

▪ **Claim Rejections - 35 USC § 102(b) over Skinner (USPN 6,210,710):**

Applicant argued, "Skinner discloses a composition comprising at least first and second components and a medicament, where the first component is selected from derivatives of hydroxypropylcellulose (HPC), ethylcellulose (EC) and hydroxyethylcellulose (HEC) and the second component is at least one other polymer. Gellan gum is included in a list of suitable polymers. However, Skinner fails to disclose the compositions of the present invention, comprising gellan gum and one or more hydrophilic polymers selected from guar gum, hydroxypropyl methylcellulose, carboxymethyl cellulose sodium salt and xanthan gum.

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Moreover, Skinner does not provide any working example in which the composition includes gellan gum. Thus, it cannot be held that Skinner discloses the present invention.”

Applicant’s arguments have been fully considered and were found to be persuasive by virtue of the amendment to the claims. Accordingly, the 35 U.S.C. 102(b) rejection over Skinner has been withdrawn.

▪ **Claim Rejections - 35 USC § 102(b) over Illum (USPN 5,935,604):**

Applicant argued, “Illum provides a nasal drug delivery composition comprising nicotine and ion-exchange material which forms a complex with the nicotine, such as a polymer material or bioadhesive microsphere. Illum does not relate to an orally administered dosage form for a gastric environment. We note that Illum’s claims recite ‘for nasal administration’”.

Applicant’s arguments have been fully considered and were found to be persuasive by virtue of the amendment to the claims. Accordingly, the 35 U.S.C. 102(b) rejection over Illum has been withdrawn. However, this rejection has now been reformulated as a 35 U.S.C. 103(a) rejection over Illum. Applicant argues, “Illum does not relate to an orally administered dosage form for gastric environment”. It is the position of the Examiner that while Illum is not directed to "oral" usage, Applicant's limitation of a dosage form "suitable for oral administration" is deemed a future-intended use of the dosage form and therefore does not impart patentable weight to the claim. The fact that the instant invention is aimed at oral administration does not negate the teachings of the Illum reference and does not distinguish over Illum. A product is being claimed herein of which Illum explicitly teaches a controlled release drug delivery composition comprising polysaccharides and suitable polymeric materials of which include gellan gum,

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alginate, carboxymethylcellulose (CMC), xanthan gum, agar, guar derivatives and the like. Thus, Illum teaches a formulation having the required materials (i.e., polymers, gellan gum, drug, etc.) as that instantly claimed herein. Accordingly, Illum renders the instant invention prima facie obvious. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

▪ **Claim Rejections - 35 USC § 103(a) over Skinner (USPN 6,210,710):**

Applicant argued, “In light of the claim amendment, and for the same reasons identified with respect to the alleged anticipation by Skinner, we believe this rejection is now moot.”

Applicant’s arguments have been fully considered but were not found to be persuasive. Skinner teaches a sustained release pharmaceutical composition comprising a polymer blend formed with a medicament present in a therapeutic amount wherein the polymer blend contains at least a first component and a second component (see column 1, line 4 - col. 2, line 4). Various polymers may be used in the matrix blend of the invention and include hydroxypropylcellulose (HPC), ethylcellulose (EC), hydroxypropylmethylcellulose (HPMC), carboxymethylcellulose (CMC) and the like (col. 2, line 51 – col. 3, line 63). With respect to the inclusion of gellan gum, Skinner teaches polysaccharides employed in the invention, which are disclosed at column 2,

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line 64 – col. 3, line 24 and include, for example, gellan gum, guar/guar derivatives, xanthan gum, agar, algin, starch, modified starches and the like. See also claim 1 at column 13. These ingredients can be used alone or as mixtures thereof. These ingredients read on the gellan gum and hydrophilic polymers of instant claims 1 and 3. Thus, while gellan gum is not disclosed in the example(s), Skinner nonetheless clearly teaches the incorporation of gellan gum, which is deemed suitable and beneficial for their formulation. Hence, the instant invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, given the explicit teachings of Skinner. Skinner teaches a controlled release matrix dosage form comprising the inclusion of polysaccharides (i.e., gellan gum, guar gum, xanthan gum and mixtures thereof) in combination with hydrophilic polymers (i.e., CMC, HPMC, etc.) and active ingredients (i.e., anti-infectives). Excipients and additives are also included in the formulation. The dosage forms are suitable for oral administration such as in the form of tablets.

This rejection has been maintained herein.

▪ **Claim Rejections - 35 USC § 103(a) over Baichwal (5,958,456) in view of Skinner (USPN 6,210,710):**

Applicant argued, “The dissolution profiles of the formulations of Baichwal are given in examples 1-12, all of which include a hydrophobic polymer within the formulation. Baichwal is completely silent concerning gellan gum. Even if the gellan gum taught by Skinner was used in the formulation of Baichwal, the formulation would include a hydrophobic polymer in accordance with the teachings of Baichwal and the hydrophilic matrices of the present invention would not be obtained.”

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Applicant's arguments have been fully considered but were not found to be persuasive. It is noted that the formulations of Baichwal include the use of a hydrophobic polymer. However, the argument that "Even if the gellan gum taught by Skinner was used in the formulation of Baichwal, the formulation would include a hydrophobic polymer in accordance with the teachings of Baichwal" was not persuasive since the instant claims do not preclude or exclude the use of hydrophobic polymers, such as those disclosed by Baichwal. In this regard, the instant claims utilize "comprising" claim language and thus permit the presence of additional components besides from those instantly recited (including the hydrophobic polymers of Baichwal). The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising, 'the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). Hence, in view of the open claim language, which does not exclude the inclusion of additional, unrecited elements (i.e., the hydrophobic polymers of Baichwal), the instant invention is rendered prima facie obvious given the combined reference teachings of Baichwal and Skinner.

This rejection has been maintained herein.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claim 11 drawn to an invention nonelected with traverse in the reply filed on 01/15/10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 3-8, 10 and 12 are rejected.

Claim 11 has been withdrawn.

Claims 2 and 9 have been cancelled.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

December 19, 2010

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